K120299
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MAY 18 2012

**510(k) SUMMARY**

**Medigus' SRS Endoscopic Stapling System**

## I. SUBMITTER

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Date Prepared: May 16, 2012

## II. DEVICE

### Name of Device and Name/Address of Sponsor

Medigus Ltd.
7A Industrial Park,
P.O. Box 3030
Omer 84965,
Israel

### Common or Usual Name

SRS Endoscopic Stapling System (abbreviated in this document to 'SRS')

### Classification Name

Endoscope and Accessories (21 CFR §876.1500)

Regulatory Class: II

Product Code: ODE

## Predicate Devices

Endoscopic Plication System, also referred to as Plicator™, manufactured by NDO Surgical Inc. of Mansfield, Massachusetts, cleared under 510(k) #K023234, #K031262 and #K071553.

EsophyX System with EGS SerosaFuse™, manufactured by EndoGastric Solutions Inc. of Redmond, Washington and cleared under 510(k) # K071651.

## Intended Use / Indications for Use

The SRS Endoscopic Stapling System is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease (GERD) in patients who require and respond to pharmacological therapy.

## Technological Characteristics

The Medigus SRS is an Endoscopic Stapling System. The device consists of the following components and accessories:

- The flexible endoscope combines a video camera, ultrasound sensor (range finder) and a stapler mechanism. The distal end of the endoscope is capable of retroflexion. The system enables creation of an endoluminally anterior partial fundoplication by stapling together the soft tissue of the fundus (upper part of the stomach) and the esophagus.

- The endoscopy suite includes the ISL (Insufflation, Suction and Light) console and the CCU (Camera Control Unit) console.

- The associated accessories include:

    - Irrigation bottle with liquids for irrigation of the camera lens
    - Suction canister for extracting liquids during the procedure
    - Silicon tubes for connecting the ISL and other accessories to the endoscope
    - Disposable air filter of the suction ISL input channel
    - Overtube for protecting patient's pharynx

## Comparison of Technological Characteristics with Predicate Devices

The candidate device and both predicate devices are based on the same technological elements:

- Endoscope – used to reach the target tissue
- Device inserted through an overtube – to protect the esophagus
- Creation of a gastric (or gastroesophageal) plication in close proximity to the gastroesophageal junction – either by the retroflexed device (SRS and EsophyX) or by a retractor (Plicator)
- Use of a permanent implant made of titanium (SRS, EPS) or polypropylene (EsophX)
- Delivery of the elements needed to complete the procedure through the endoscopic device

- Visual control of the device's position and orientation before releasing the implant; an ultrasound range-finder provides added positioning accuracy for the SRS system
- Use of a mechanical component for positioning and launching the implant: a stylet (EPS, EsophyX) or positioning screws (SRS)
- User-controlled mechanical trigger (or knob) to launch the fastener (implant)
- Mechanically securing the plication by a permanent implant fastener (SRS and EsophyX) or a sutured bridge (EPS)

The candidate and predicate devices have the same principle of operation, using a device-delivered, permanent implant to secure a plication, intended to create an anatomical fold that will serve as a valve close to the gastroesophageal junction, thereby preventing flow of gastric contents into the esophagus. The unique aspects of SRS are intended to improve the precision of positioning the anvil and cartridge (ultrasound range finder) and the use of staples as fasteners.

The use of staples for permanently attaching soft tissues is a well-established surgical technique. The specific staple used in the SRS System is substantially equivalent to the Auto Suture Surgical Staples manufactured by United States Surgical of Norwalk, Connecticut and cleared by FDA under 510(k) #K013860 on December 19, 2001.

Neither element represents a significant change in the principle of operation or the technological manifestation of the device, and therefore the candidate device is substantially equivalent to the predicate devices in its technological features.

## Performance Data

The following performance data was provided in support of the substantial equivalence determination.

### Biocompatibility testing

The biocompatibility evaluation program for the SRS System was based on demonstrating compliance with FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, May 1, 1995 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The testing program included cytotoxicity, sensitization, irritation, and pyrogenicity.

### Electrical safety and electromagnetic compatibility

Electrical safety and electromagnetic compatibility (EMC) testing was conducted on the SRS System, consisting of the ISL console, the CCU console and endoscope. The system complies with the IEC 60601-1, IEC 60601-2-18 and IEC 60601-2-37 standards for safety and the IEC 60601-1-2 standard for EMC,

### Mechanical and acoustic testing

Following a detailed risk analysis, a series of mechanical tests concerning the manual operation of the system and its mechanical performance were formulated. The system successfully passed all the mechanical tests. The acoustic transducer included in the system was tested to its specifications.

## Animal testing

In the course of the development of the device, Medigus conducted numerous tests with prototype devices on a porcine model. These included survival and non-survival studies, as well as staple longevity for up to 13 months.

All of these experiments were carried out at the Animal Research facility of the Institute for Animal Research, Lahav, Israel, and were authorized, according to the Israeli animal welfare act, by the institutional review board for animal research of the faculty of the health sciences of Ben-Gurion University of the Negev, Beer Sheva, Israel.

The main animal study was performed in conformity with GLP standards by an external subcontractor (ECON AG Mecklenbureger str. 233 D-23568 Lubeck, Germany). The experiments were conducted at the animal research facilities of the Virchow Institute in Berlin, Germany. The complete study report was submitted in the original IDE (G070138).

In the GLP animal study, 16 pigs underwent endoscopy with the SRS System. Twelve pigs underwent fundoplication, and 4 pigs served as a sham (control) group. There were no procedure related complications or mortality in this study, at 2, 4 and 6 weeks follow-up (4 in pigs in each group).

The safety and feasibility of the Medigus SRS device were evaluated by macroscopic and histological evaluation of the tissue in the treatment stapled areas.

These studies demonstrated that the Medigus SRS® device can safely create an anterior partial fundoplication, equivalent to that which is constructed using conventional laparoscopic or open surgical techniques.

## Clinical testing

Clinical testing of the device included an initial feasibility study of 6 patients, a pilot study consisting of 13 patients and a pivotal study of 72 patients.

### Pilot Study

All pilot-study patients were treated with the SRS and recovered from the procedure without sequelae. There was one anticipated procedure related adverse event, benign pneumoperitoneum, which resolved spontaneously within 48 hours.

The main success criterion of the pilot study, improvement in GERD HRQL score by 50% or more at six weeks post-procedure, was met by 12 of the 13 subjects, and was very close to 50% (48.3%) in the thirteenth patient. All subjects reduced their PPI use. Twelve of the subjects were off daily PPI and met the secondary success criterion (reduction to < 50%). Eight subjects were off any GERD related medications.

The pilot study suggested that the SRS is comparable to other endoscopic procedures or laparoscopic surgery procedures in terms of safety and effectiveness.

**Pivotal Study**

In the pivotal study of 72 patients, following the surgical procedure performed by the SRS Endoscopic Stapling System, patients were followed for a period of six months.

**Safety**

The SRS study reported ten patients with a total of ten serious adverse events. Four events were considered 'mild' in intensity, involving pain and fever. Three events were classified as 'moderate' in intensity, involving pneumothorax, pneumomediastinum, pneumoperitoneum (all resolved spontaneously). Two events were considered 'severe' in intensity: one involved esophageal perforation (required drainage) and another had suicidal thoughts (non-device/procedure related). The intensity of one SAE that involved GI bleeding and required a transfusion, was not classified. Six of the SAEs were considered related to the device – one definitely (esophageal perforation) and the others possibly. Three events were considered not related to the device. The median time from procedure to SAE was 1.5 days for events related to the device. None of the patients with SAEs required any operation or re-operation.

Adverse events reported in the SRS that occurred in greater that 5% level were postoperative pain or discomfort in 33%, postoperative nausea in approximately 10%, and sore throat in 21%. The adverse events were mild or insignificant in most cases.

The SAE and overall safety profile were similar to the Esophyx predicate device for which two perforations and one bleeding were reported.

The number of AEs was similar to those reported for the EsophyX and Plicator: Three cases of fever were reported in the current study (for 72 patients), similar to the 3 cases of fever reported for EsophyX. There were 23 cases of chest pain (23/72 = 32%) vs. 17% reported for Plicator; whereas abdominal pain was recorded for 44% of the patients for Plicator and 15% of the patients that underwent EsophyX treatment. Sore throat was reported for 15 patients (15/72 = 21%) vs. 15% for Plicator and 8% for EsophyX. EsophyX also reported 7% of nausea events and 4% of dysphagia, whereas there were no reports of dysphagia in the current study and only 7 (7/72 = 10%) reports of nausea (there were also two reports of vomiting).

In summary, the adverse events and serious adverse events recorded in the study were similar in nature and frequency to those reported for the predicate endoscopic fundoplication systems. Therefore the clinical results reported for this study documented the safety and effectiveness of the SRS system for its intended use.

**Efficacy**

The primary endpoint for the SRS study focused on the GERD-HRQL score. The study results show that 75% of the patients had a >50% improvement in their GERD-HRQL score off PPI at six months compared to baseline. Hence the study met its primary endpoint with the required 95% confidence level.

The reduction in the median score for the SRS of 23.0 units (from 29.0 to 6.0) represents a 79.3% improvement. This value is almost identical to the result reported by Cadiere et al (1) for the pivotal trial of the EsophyX system (79.2%), and slightly better than the result reported by Von Renteln et al

(2) for the NDO Plicator (76.0%). Therefore, the efficacy of the SRS system in successfully treating chronic symptoms of GERD is similar to the efficacy reported by both predicate devices.

The median value of the percent of time pH < 4.0 decreased from an initial value of 8.3% at baseline to 6.75%. Therefore, the study met its secondary endpoint related to the acid exposure test. A comparison to similar results reported in the literature revealed that the change in the median values for the EsophyX system (1) showed a decrease of 31%, a decrease of 18% for the Plicator (2) with a corresponding decrease of 19% for the SRS system. Hence, the SRS results in reducing the exposure to gastric acids are similar to those reported for the Plicator system and are lower than those reported for the EsophyX system.

In summary, based on the clinical performance as documented in the prospective, multi-site clinical trial, the SRS system was found to have a safety and efficacy profile that are substantially equivalent to those of the predicate devices.

## Substantial Equivalence

The SRS is as safe and effective as the predicate devices – Endoscopic Plication System (and Plicator) by NDO Surgical Inc. and the EsophyX System with EGS SerosaFuse by the EndoGastric Solutions Inc. The SRS has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the SRS and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the SRS is as safe and effective as the Endoscopic Plication System and the EsophyX System with EGS SerosaFuse. Thus, the SRS is substantially equivalent.

**REFERENCES**

1. Cadière GB, Buset M, Muls V, Rajan A, Rösch T, Eckardt AJ, Weerts J, Bastens B, Costamagna G, Marchese M, Louis H, Mana F, Sermon F, Gawlicka AK, Daniel MA and Devière J. Antireflux Transoral Incisionless Fundoplication Using EsophyX: 12-Month Results of a Prospective Multicenter Study. World Journal of Surgery (2008) 32:1676-1688.
2. Von Renteln D, Schiefke I, Fuchs KH, Raczynski S, Philipper M, Breithaupt, W, Caca K and Neuhaus H. Endoscopic full-thickness plication for the treatment of GERD by application of multiple Plicator implants: a multicenter study. Gastrointestinal Endoscopy (2008), 68(5):833-844.

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MAY 18 2012

Re: K120299
Trade/Device Name: SRS Endoscopic Stapling System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated: May 1, 2012
Received: May 1, 2012

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K120299

Device Name: SRS Endoscopic Stapling System

Indications for Use: The SRS Endoscopic Stapling System is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease in patients who require and respond to pharmacological therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K120299